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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEINSTEIN, LEONARD J

ART UNIT

PAPER NUMBER

3746

MAIL DATE

DELIVERY MODE

11/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,990	Applicant(s) DEMERS ET AL.	
	Examiner LEONARD J. WEINSTEIN	Art Unit 3746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment of June 30, 2008. In making the below rejections and/or objections the examiner has considered and addressed each of the applicant's arguments.
2. The examiner acknowledges the amendments to claims 1-4, 7, and 9-23. The examiner notes claims 26 and 27 have been introduced.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 9, 16, 23, and 26 are rejected to because the claims omit language which clearly defines essential elements and aspects of the invention which the applicant has attempted to claim.

As best understood by the examiner, the applicant has attempted to present a limitation that is directed toward the feature of each cassette having an exclusive functional relationship with a separate individual pump and subsequently each individual pump having an exclusive functional relationship with a respective cassette.

The examiner notes that the language of "membrane pump cassettes for use respectively with the plurality of pumps...under control of its respective pump" common to claims 1, 9, 16, 23, and 26, is vague and unclear. Further the language does not limit

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each pump to have a mutually exclusive functional relationship with a single cassette.

While it is clear that each cassette is operated by at most one of the pumps within the “plurality of pumps,” therefore being “its respective pump,” the limitations only define the relationship of components with respect to the cassette. Therefore given the broadest reasonable interpretation of the limitations as claimed, several cassettes could be used with a single pump as long as they were only used by one pump. Conversely the pump is not limited to be used with only one cassette.

6. Claim 2 recites the limitation “the inlet tube attachment” in line 3. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 3 recites the limitation “attachments” in line 3. There is insufficient antecedent basis for this limitation in the claim. For the purposes of clarity and the office action on the merits the limitation of “attachments of the plurality of membrane pump cassettes” will be considered to be --- an attachment for each of the plurality of pumps ---.

8. Claim 9 recites the limitation “first pump chamber” in line 8. There is insufficient antecedent basis for this limitation in the claim. For the purposes of clarity and the office action on the merits the limitation of “first pump chamber” will be considered to be --- working solution pump chamber ---.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 6-7, 9-11, 13-14, 23-24, and 26-27 are rejected under 35

U.S.C. 102(b) as being anticipated by Cote et al. US 6,214,231. Cote teaches all the limitations as claimed for an apparatus (such as membrane cassette bank or a "kit") having a plurality of pumps including: **[claims 1, 9, 23, and 26]** a plurality (**claim 9** - capable of being an odd number – col. 7 ll. 36-39) of membrane pump cassettes (11/12) for use respectively with the plurality of pumps (20, 25, 27), each membrane cassette (11/12) comprising a first (working solution) pump chamber 13 at least partially comprising a membrane (body of element 13) for pumping fluid (working solution) under control of its respective pump (one of elements 20, 25, 27) and a first fluid (working solution) inlet port (one of element 62 as shown in figure 4 and being connected to tubing connection between element 11 or 12 and element 42) in selective fluid communication with the first (working solution) pump chamber 13 wherein fluid (working solution) enters the first (working solution) pump chamber 13 when its respective pump (20 of 20, 23, and 27) applies negative pressure (col. 7 ll. 6-8) to the first (working solution) pump chamber 13 membrane (body of element 13), an (working solution) inlet tube, a first instance of the branch conduit 66 connected to the conduit between element 11 or 12 and element 42, and distribution tubing 41 that connects the (working solution) inlet tube, a first instance of the branch conduit 66 connected to the conduit between 11 or 12 and 42, to the first fluid (working solution) inlet port 62 of each of the pump cassettes (11/12) such that the first (working solution) pump chambers 13 of the pump cassettes (11/12) can be coupled to pump fluid (working solution) from a

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common fluid (working solution) source (30 or 40) via the (working solution) inlet tube (a first instance of the branch conduit 66 connected to the conduit between 11 or 12 and 42) and distribution tubing 41, and **(claim 9)** and the working solution inlet tube, a first instance of the branch conduit 66 connected to the conduit between element 11 or 12 and element 42, can join the distribution tubing 41 proximate to a junction between the distribution tubing 41 to a middle one of the membrane pump cassettes (11/12) such that connected to the distribution tubing 41 on either side of the junction are an equal number of the membrane pump cassettes (11/12 – col. 7 ll. 36-39); **[claims 2 and 10]** an inlet tube (a first instance of the branch conduit 66 connected to the conduit between 11 or 12 and 42) is centrally attached along the distribution tubing 41 and the plurality of membrane pump cassettes (11/12) are symmetrically attached to the distribution tubing 41 with respect to a inlet tube attachment (connection between element 41 and element 42), **(claim 10)** as would be the case for the cassettes (11/12) on the other side of a junction; **[claims 3 and 11]** wherein an attachment for each of the plurality of membrane pump cassettes to the distribution tubing 41 are equally spaced apart along the distribution tubing 41; **[claims 4, 12, and 24]** a plurality of incubation bags 19, each bag being attached to an outlet port 16 on a respective one of the membrane pump cassettes (11/12); **[claims 6 and 13]** a break-away closure 42 on the inlet tube (a first instance of the branch conduit 66 connected to the conduit between element 11 or 12 and 42); **[claims 7 and 14]** each membrane pump cassette (11/12) includes a second fluid inlet port (one of element 62 not being the first instance), as defined by any of with a second fluid inlet tube, (a second instance of the branch conduit 66 connected to the

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conduit between element 11 or 12 and element 42) attached thereto and further including a break-away closure 42 on the second fluid inlet tube (a second instance of the branch conduit 66 connected to the conduit between element 11 or 12 and element 42); **[claim 27]** wherein fluid exits the first pump chamber (body of 13) when its respective pump (20) applies positive pressure to the first pump chamber membrane (body of 13).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cote et al. 6,214,231 in view of Grim et al. 6,245,570. Cote teaches all the limitations as discussed but does not teach the limitation of a bar code label on each of an incubation bags as taught by Grim '570, with element 40 shown on Figure 1. A bar code label 40 applied to an incubation bag Cote would provide for a means to track the

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container and what it holds when used in conjunction with a computerized inventory system (col. 2 ll. 2-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a bar code label of Grimm, on the incubation bags of Cote, to provide a means for indexing the location, process, and substance associated with each container (Grimm col. 2 ll. 2-7).

Allowable Subject Matter

14. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim 1. The limitations of claim 1 being required to be re-written to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph before incorporation.

15. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim 9. The limitations of claim 9 being required to be re-written to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph before incorporation.

16. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim 23. The limitations of claim 23 being required to be re-written to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph before incorporation.

17. Claims 8, 15, and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim, including the examiner's suggested language below, and any intervening claims.

The mutually exclusive relationship between each cassette and its pump and pump with its cassette is essential to invention as disclosed. A clear limitation directed toward this feature would aid in defining over the prior art. The examiner notes that a clear limitation directed toward this feature would not by itself, define claims 1, 9, and 23 over the prior art. However the proposed language would put claim 16 in condition for allowance, as indicated below. In an effort to further prosecution, the examiner suggests adding to each of claims 1, 9, 16, and 23, the limitation of:

- --- there being a single membrane cassette for use with a separate pump within the plurality of pumps and each separate pump operates a single membrane cassette---

Claims 8, 15, and 25 would be in condition for allowance if each was rewritten to include all of the limitations of claims 1, 9, and 23 respectively, modified to include the language above, or a slight variation thereof to accommodate for like elements defined by different terms.

18. Claim 16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. The rejection of claim 16 would be obviated if the claim were amended to include the language suggested above in item 14 of this action. Claims 17-22 are objected to as being dependent upon a rejected base claim.

Response to Arguments

19. Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEONARD J. WEINSTEIN whose telephone number is (571)272-9961. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Kramer can be reached on (571) 272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Devon C Kramer/
Supervisory Patent Examiner, Art
Unit 3746

/Leonard J Weinstein/
Examiner, Art Unit 3746